Accelerating the Development of the **eHealth Market** in Europe

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Executive summary

This report on lead market opportunities for eHealth proposes actions aiming at accelerating the development of the European eHealth market, increasing economic benefits and simultaneously developing the quality of health products and services. The prospective return on investment of eHealth is relatively high when compared to the costs inherent in the health sector.

A "lead market" can be defined as a market for innovative products and services or technological solutions with high growth potential; a market where EU industry can develop competitive advantage to lead in international markets; a market that requires action by the public authorities to deal with regulatory obstacles.

The above definition of Lead Market is the backbone of this paper, which assesses the driving factors related to the eHealth market, its potential in terms of growing demand and market growth opportunities, changing demographics and disease patterns, and healthcare capabilities in eHealth. Subsequently, the paper illustrates the eHealth market's incoherent positioning throughout Member States as well as the latent market areas. Structural barriers delaying successful market breakthrough, such as market fragmentation, lack of financial support and procurement issues, which collectively affect the development of demand for eHealth products and services, are thoroughly considered. The paper points out the positive impacts to be expected from eHealth, including strategic (competitive advantage and interoperability leading to technology advances), economic (economies of scale) and social (improvements in service level and access to health services).

A discussion on public intervention in view of achieving positive outcomes is conducted throughout the paper and the role of public authority is recognised as imperative in reducing existing barriers. eHealth is considered as the key factor in decreasing the costs for healthcare; however a suitable legal and regulatory framework is indispensable.

The main outcome of this paper is a roadmap on policy recommendations, directed at specific stakeholders, including industry representatives, EU Commission working groups, the i2010 group on eHealth, Member States and various eHealth stakeholder groups. The recommendations highlight the main areas of intervention over the period 2008-2010, and focus on dealing with the identified obstacles:

1) Reducing market fragmentation and lack of interoperability through pilots, benchmarking, standardisation and certification; 2) Improving legal certainty and consumer acceptance by disseminating information, best practice, guidelines, recommendations and implementing screening tools; 3) Facilitating access to funding through increased visibility and training, workshops, improved cooperation, testing & pilots and guidance on financing; 4) Improve procurement by facilitating the expression of public demand through more innovation-friendly procurement activities.
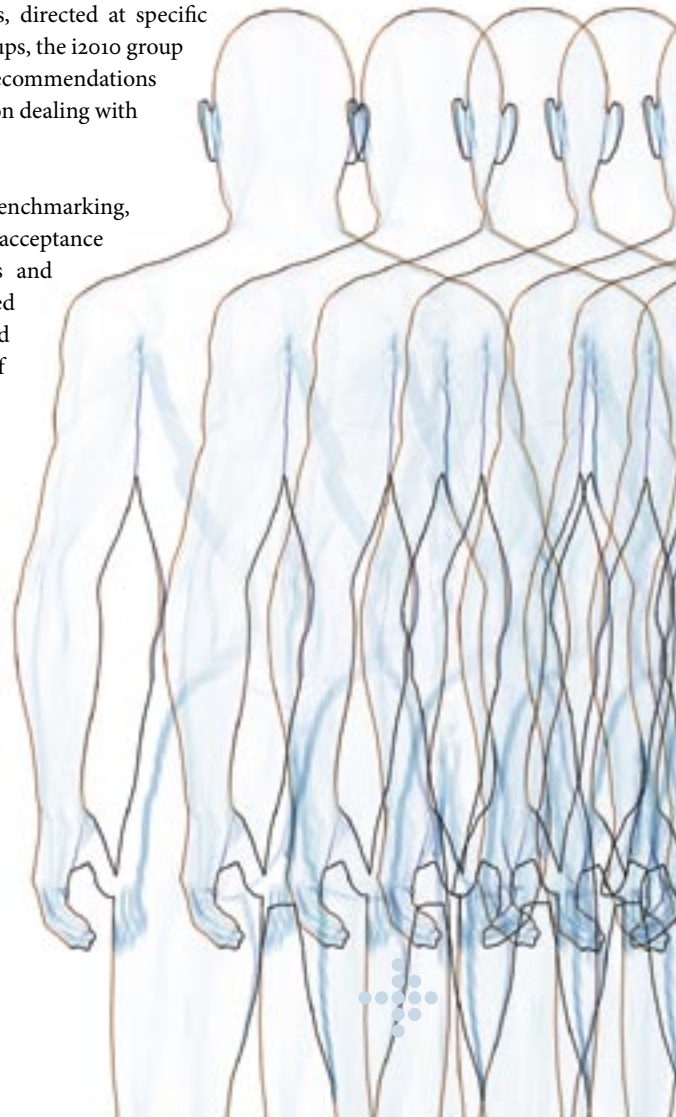
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Introduction

The January 2006 Aho Report on "Creating an Innovative Europe"[1] recommended the development of innovation-friendly markets in a more targeted way by creating conditions to facilitate the translation of technological and non-technological innovation into commercial products. The Aho Report explicitly acknowledged **the importance of information and communication technologies (ICT) in tackling specific challenges within the healthcare sector, and thus identified eHealth (also referred to as ICT for Health) as an example of a key area where a market for innovation can operate and public policy can have a significant role**. The Commission subsequently proposed a new Lead Market Initiative aiming to facilitate the creation and marketing of new innovative products and services in promising areas.

The December 2006 Competitiveness Council agreed to launch an initiative as a new policy approach aiming at the creation of markets with high economic and social value, in which European companies could develop a globally leading role, removing burdensome regulation or systemic failures in policy and legislative coherence which might hamper this potential.

The Commission has been invited to elaborate a valid approach for fostering the emergence of lead markets by identifying areas where concerted action that would take place through key policy instruments and framework conditions can speed up market development.
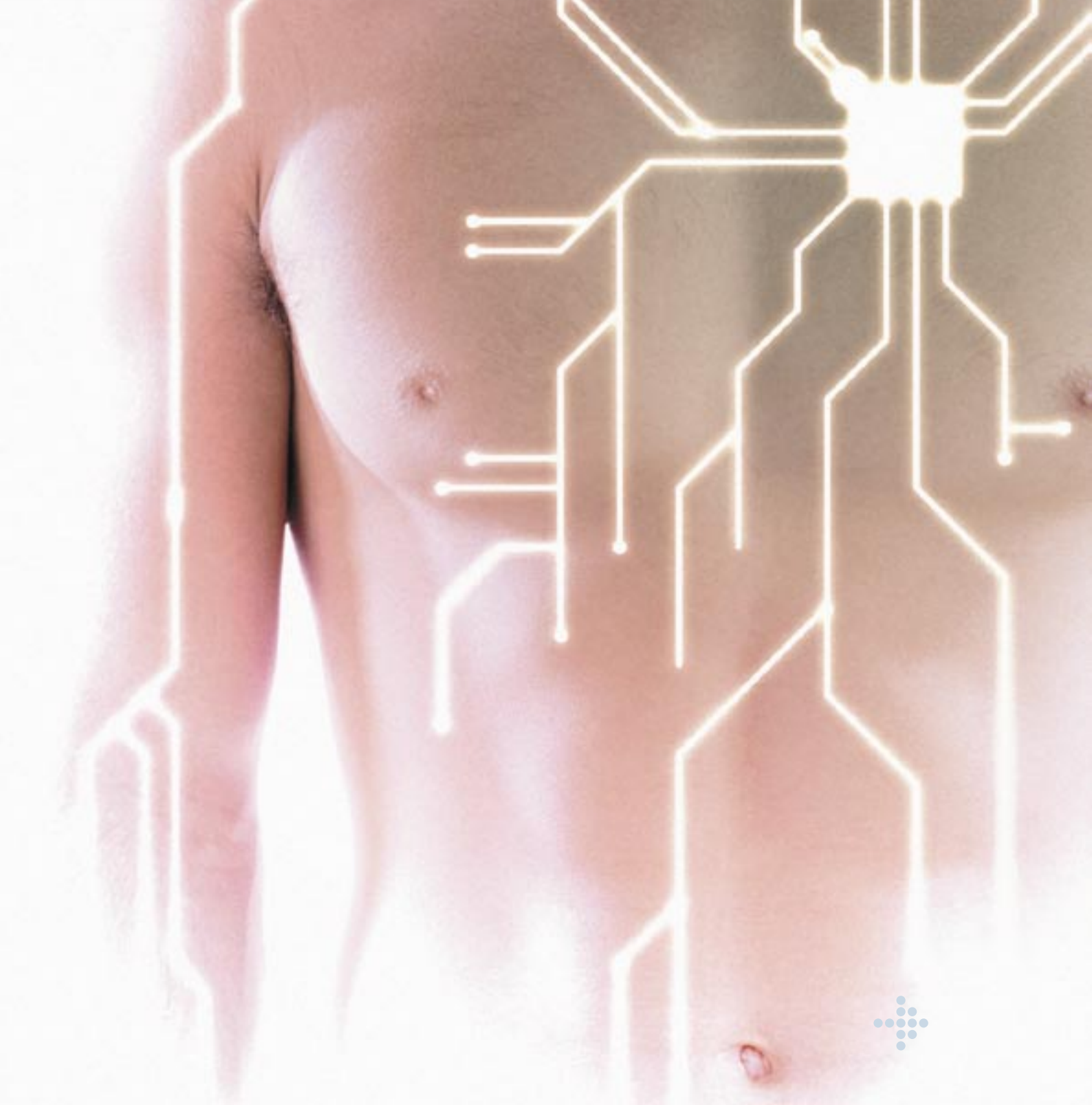
A "lead market" can be defined as a market:

1. for innovative products and services or technological solutions with high growth potential (with the potential based on increasing public and private customer need/demand);
2. where EU industry can develop competitive advantage to lead in international markets (EU knowledge and industrial basis would capitalise on investments in promising new technologies);
3. that requires action by the public authorities (as a regulator lifting obstacles, as a customer driving developments, or as a facilitator).

The Lead Market Initiative is not about "picking winners". Rather it is about identifying example areas with greatest potential for adding value to European economy. It is also not about artificially creating markets for research results. Rather, it is about creating a business environment that enables industry to develop and commercialise innovative products and services on a competitive basis.

Consequently the Lead Market Initiative on eHealth shall focus on:

- a definition of the scope of the eHealth market products and services (providing evidence of emerging market segments); and identification of the existing policies, policy instruments and regulatory frameworks;
- a proposal for a new policy-coordination approach based on a better balance between supply and demand both between and within Member States (providing evidence of expected influence of public action) in a specific focus area for eHealth - namely, telemedicine and personal health systems;
- elements of validation by external stakeholders (providing evidence of industry commitment);
- a proposal for a road map with measurable actions and binding targets.

To structure this proposal, this report on the lead market opportunities for eHealth defines the concept of an eHealth market for Europe. It provides an analysis of the market's potential, including the barriers that need to be overcome, which are composed of the current eHealth market fragmentation and lack of interoperability, aspects of legal uncertainty around eHealth, insufficient financing mechanisms, and procurement practices that do not cater for innovation, before it outlines the market's strategic, economic, and social benefits. It details very specifically the four approaches necessary to overcome any barriers or obstacles to eHealth lead market creation. The validity of this analysis is supported by a description of the important level of consultation undertaken in the preparation of this document. Finally, a precise roadmap of activities proposed for the years 2008-2010 is outlined.

Definition of the eHealth Market

The eHealth market can be defined as comprising the following four interrelated major categories of applications[2]:

1. Clinical information systems
    a) Specialised tools for health professionals within care institutions (e.g., hospitals). Examples are Radiology Information Systems, Nursing Information Systems, Medical Imaging, Computer Assisted Diagnosis, Surgery Training and Planning Systems.
    b) Tools for primary care and/or for outside the care institutions such as general practitioner and pharmacy information systems.

2. Telemedicine and homecare, personalised health systems and services, such as disease management services, remote patient monitoring (e.g. at home), tele-consultation, tele-care, tele-medicine, and tele-radiology.

3. Integrated regional/national health information networks and distributed electronic health record systems and associated services such as e-prescriptions or e-referrals.

4. Secondary usage non-clinical systems
    a) Systems for health education and health promotion of patients/citizens such as health portals or online health information services.
    b) Specialised systems for researchers and public health data collection and analysis such as bio-statistical programs for infectious diseases, drug development, and outcomes analysis.
    c) Support systems such as supply chain management, scheduling systems, billing systems administrative and management systems, which support clinical processes but are not used directly by patients or healthcare professionals.

eHealth can thus be said to cover the interaction between patients and health-service providers, institution-to-institution transmission of data, or peer-to-peer communication between patients and/or health professionals; it can also include health information networks, electronic health records, telemedicine services, and personal wearable and portable communicable systems for monitoring and supporting patients.

2 Analysis of the eHealth market potential

Growing demand for innovative eHealth products and services

The health sector in the European Union (EU) employs almost 10% of the total workforce and corresponds to almost 9% of gross domestic product (GDP). Health spending is rising faster than GDP and it is estimated to reach 16% of GDP by 2020 in OECD countries[3]. These figures present grave challenges to the sustainability of current health and social care systems unless counterbalancing action is taken.

The eHealth industry in the EU 15 was estimated to be worth close to €21 billion in 2006[4]. This figure covers all four areas mentioned in the eHealth market definition (see section 1) including the ICT infrastructure of organisations belonging to health delivery system. It does not cover the ICT systems and services of the wellness sector[5].

Over the last 25 years, healthcare has fallen progressively behind other service sectors in terms of relative levels of ICT investment. Despite efforts to justify higher expenditures, typical European investment levels in healthcare ICT remained static for a long time at around 1% of total revenue[6], and reached an average 2% more recently[7]. The major part (close to 80%) of the eHealth market figure represents the generic ICT infrastructure (networks, communication, hardware, software for the back office management) described in the fourth of the market categories outlined in section 1. However, all market players and observers agree that eHealth in Europe is set for explosive growth, driven by the need to face the health-related challenges (described later in this section) and to take advantage of burgeoning new medical information and communication technologies.

Recent research has suggested that the health ICT industry has the potential to be the third largest industry in the health sector with a global turnover of €50-60 billion, of which Europe represents one third[8]. By 2010, a double digit growth rate of up to 11% is foreseen as driven by a search for more productivity and performance[9]. However, this potential growth might not occur if the existing barriers to the market (described in section 2.3 below) are not removed.

The opportunities for market growth are clear. Real eHealth cannot happen without trading up the information capacity opportunity for health professionals. The 2005 HINE report stated: "While today over 98% of Western European hospitals with more than 100 beds have reached the basic level of sophistication with administrative solutions (PAS and departmental systems), only 18.2% have reached advanced clinical solutions in place, and a mere 2.1% use decision support solutions. European hospitals are still some way off using the full capabilities of key eHealth tools to bring added benefit and safety to Europe's healthcare systems." Also, over 80% of general practitioners are online, and broadband is available to more than 90% of the urban population, but only 60% of the rural population. While today broadband usage for health purposes remains very limited, its increased coverage will inevitably lead to more use of eHealth solutions.[10]

Potential growth is now expected in the specialised eHealth services (categories 1-3 described in section 1 above) such as e-prescriptions, deployment of electronic health records, telemonitoring and homecare as well as services and health information spaces driven by patients, for example *My HealthSpace.*[11]

Over the past years scientifically sound evidence has been accumulated through eHealth trials, pilots and prototypes that points to clear benefits from improvement in quality of care and access to healthcare, and economic improvements.[4]

There are six main factors that drive the development of the eHealth market today:

i) Political commitment expressed in national and EU-wide eHealth roadmaps. All Member States have issued roadmaps for deployment of eHealth services as a result of addressing actions in the European eHealth Action Plan of April 2004.[12] The EU currently has a worldwide momentum in the deployment of regional/national health information networks and shared electronic records for integrating care delivery across different health communities that is often supported by the use of health (insurance) cards. Furthermore, patient safety is rising up on the European agenda rapidly due to increased media coverage and healthcare costs. This results in government-backed demand for shared infrastructure, and more effective patient information sharing and management.

Further political commitment was confirmed at the eHealth Conference 2007 in Berlin in April 2007 where EU Member States agreed a declaration on European Co-operation on Europe-wide Electronic Health Services, and confirmed their intention to take steps towards implementing a roadmap for cross-border eHealth services. Specific mention was made of industry involvement:

"Industry representation is vital to this initiative. Collaboration will be enhanced between Member States and those industries considered important to these developments. eHealth business potential needs to be unlocked and a more favourable business environment created for eHealth. This engineering process will influence the efforts made by the eHealth industry to build an eHealth market in Europe, and have benefits for European employment."[13]

ii) Ageing Europe. The world population is growing while Europe's is decreasing due to ageing. The number of people over 65 will rise nearly 40% between 2010 and 2030 and the number of people over 80 will have doubled by 2050[14]. Associated with this ageing demography, the costs of healthcare are rapidly increasing while the tax base is increasingly at stake. People over the age of 65 receive four times the number of medical tests as others.[15] There will be even fewer economic "producers" to support the social and health costs related to Europe's population of retirees.

iii) Changing patterns of diseases. It is not only ageing which matters, but also the pattern of disease is changing. 60% of all deaths are due to chronic diseases.[16] This imposes even a greater workload on healthcare providers and resources at a time when mobility and individualism have diminished the traditional family carer's potential. Without actions to address these causes, deaths from chronic diseases will increase by 17% over the next 10 years. In the USA, 85% of all hospital costs and 69% of all physician costs are spent on treating chronic diseases. In Europe, chronic diseases are estimated to amount to over 70% of healthcare costs. But today, chronic diseases are not yet managed appropriately. According to the World Health Organisation (WHO), at least 80% of all cardiovascular disease and type 2 diabetes and over 40% of cancer could be avoided. At this time when the challenge for all nations is to reduce the rising costs of healthcare while delivering services with a higher level of quality, eHealth systems and services provide obvious solutions to support more personalised and disease-oriented healthcare for life-long independent living and integration across the healthcare chain.

iv) Expectations of citizens-patients. People have high expectations regarding access to best expertise, best quality of medical services, latest treatments, and safer care (that are capable of reducing medical errors that are currently responsible for twice as many deaths as road accidents) and support in long term care and independent living, as well as support in their lifestyle management.

v) Patient empowerment. In parallel with patients' own expectations, in all Member States greater attention is being paid to patient empowerment. From formerly having been purely recipients of services that have been paid for by health authorities and/or third parties and decided on by health professionals, patients are now willing and able to be more active players in the various decisions concerning their health and its management. eHealth solutions, particularly Web-based systems and applications, have been instrumental in enabling this development to occur. Being part of a market that is under strong public surveillance, the potential role of public drive and procurement should not be discarded.

vi) Demand for increased efficiency from eHealth. Because health is such an information intensive sector, it is currently estimated that redundancy and inefficiency account for 25-40% of costs.[17] eHealth is capable of providing increased efficiency in data handling and information transfer in the health field.

These six factors can be turned into significant market opportunities for eHealth systems and services within Europe for improvement of health delivery systems. As a result, of the benefits provided to the personnel working in the domain strengthened human capital can act as a major contributor of the EU internal growth. Greater attention to innovation in the fields of major and chronic diseases, such as cancer, diabetes and cardiovascular disease could reduce substantially over time the burden on care services. eHealth is a sector that benefits strongly and directly from research and technological development (RTD) but also one that triggers such development. eHealth can act as an example of 'business driving technology', thus making Europe a more competitive economy and reducing barriers to the introduction of new information and communication technologies.

The eHealth industry in Europe

The eHealth supply industry – that part of the industrial sector that has research and development, design and production facilities in Europe – is present in all four market categories described in section 1.

In terms of market size, the European eHealth industry has leading positions in emerging fields such as personalised health systems, medical equipment and in several sectors of integrated eHealth solutions. The focus is on two main areas, telemedicine/homecare and clinical information systems in the primary healthcare sector (category 1 and 2 of the market definition outlined in section 1). Those companies which have potential for success in these fields include both large European-based companies of specialised eHealth solutions that are world leaders in their fields as well as the estimated 5,000

European small- and medium-sized enterprises (SMEs) that operate in various sub sectors of eHealth.

Telemedicine and homecare is the segment with the greatest potential for financial and clinical impact,[18] and is due for immediate explosion. As Datamonitor predicts "2007 will be the year when homecare telehealth moves beyond the hype and is considered a serious solution by healthcare purchasers".

The presence of EU industry is relatively weak in more traditional fields related for example to administrative and management systems or basic computing infrastructures, and its growth potential is diverse, from organic growth to high growth. For clinical information systems outside the care institutions such as general practitioner and pharmacy information systems, penetration and usage rate is very much dependent on the country/region. Hence, growth rates differ from organic to high.

EU industry is therefore considered to be well placed to seize the new opportunities arising in these two specific sectors, and others, in the European eHealth market as well as in world markets. However, there are still critical factors that need to be addressed in order to turn this potential into reality.

Barriers affecting the development of the demand

Until now, market forces have not ensured a sufficient availability or take-up of ICT-enabled solutions for health. The major challenges are described in the eHealth Communication and Action Plan (COM (2004) 356 final). Here we focus on the following challenges that are proposed to be addressed within the framework of the Lead Market Initiative:

A) Market fragmentation and lack of interoperability
B) Lack of legal certainty
C) Insufficient availability of financial support
D) Procurement issues

Market fragmentation and lack of interoperability

A major hurdle for the further and quicker development of the eHealth sector in Europe is market fragmentation, which is often exacerbated by a lack of system interoperability (both technical and semantic). Market fragmentation in Europe, with its many small, differentiated markets, inevitably results in a lack of economies of scale for companies that offer eHealth-

related goods and services. This in turn leads to higher costs for all concerned, and a slow take-up of eHealth solutions as experience is transmitted slowly between markets in different countries.

The added value offered by a more highly developed European eHealth market could be fully exploited only if the various products and/or services can be integrated and connected, so that they work together easily and effectively while maintaining patient and professional confidentiality, privacy, and security. The roots of this interoperability initiative are grounded in the European eHealth Action Plan of April 2004[12].

The potential value of the interoperable exchange of health-related data between healthcare institutions is expected to be substantial. Recent studies[19] in the United States of America estimated that net savings from the national implementation of fully standardised interoperability between healthcare providers and five other types of organisations (such as specialists, laboratories, and insurance funds) may yield up to around $US 75 billion annually of savings, or about 5 percent of the projected $US 1.7 trillion spent on United States' healthcare in 2003. Interoperability of eHealth systems could have an impact on eradicating treatments that do not improve health status, are redundant, or are not appropriate for patients' conditions which are estimated, by other studies, at costing between 20-30% of American healthcare spending, or up to $US300 billion each year.[20]

Lack of legal certainty

There is currently considerable legal uncertainty in the eHealth domain. Interoperable eHealth services cannot be fully operational without the underpinning legal certainty. Legal certainty is a pre-requisite for businesses to invest in innovation and for buyers and users to take up new products and services for which they know in advance who has legal responsibility for each aspect of an application. The public authorities have a clear responsibility in providing such certainty.

The eHealth market, due to its hybrid character that consists of competences in health policy, ICT and R&D, is an area which generates specific concerns. Uncertainties relate, among others, to issues such as the legal definition of eHealth products and services and their interoperability, patient mobility including cross-border mobility, and privacy and personal data.

The EU Member States have the prime responsibility for protecting and improving the health of their citizens. As part of that responsibility, it is for them to decide on the organisation and delivery of health services and medical care (Art. 152 TEC). However, when exercising these competences, Member States nonetheless have to comply with Community law[21]. There are a number of examples in the health area on which Member States cannot act

alone effectively and where cooperative action at the EU level is indispensable, including regarding issues with a cross-border dimension or relating to the free circulation of persons within the single EU market. The importance of cross-border healthcare was particularly addressed by the European Parliament Resolution of 24 May 2007[22] which states the following: "whilst health care systems are not a competence of the Community, issues relating to health care systems, such as access to medicines and treatments, patient information, and the movement of insurance companies and health professionals, have a cross-border character and therefore those issues need to be addressed by the Union." The European Parliament particularly noted that in order to cut the red tape relating to the use of cross-border health services, it is necessary to improve the electronic systems of patient identification and patient claims for reimbursement. It also invited the Commission to encourage the Member States to support actively the introduction of eHealth and telemedicine services.

The need for legal certainty has been highlighted in recent years through the increased political focus on cross-border care and patient mobility, of which the eHealth market can be a prime facilitator. Health systems and health policies across the EU are becoming more interconnected than ever before. Approximately 1%[23] of total healthcare expenses is spent each year on cross-border care and, although the overall number of citizens using cross-border care remains relatively low, its importance for individuals can be high. This phenomenon is set to increase with the application of the full mobility of citizens, the forthcoming liberalisation of services[24], deployment of new medical technologies and techniques through ICT, and the recent enlargement of the EU.

The differences in the costs of providing health treatment, and disparities in personal income, among Member States result in the mechanisms that are used to pay for cross-border care having different impacts for both public funds and citizens; these depend especially on the relative levels of the cost of care in the patients resident country and its cost abroad. Application of eHealth services can be considered as one of the key means to satisfy the need to decrease the costs for healthcare, while at the same time to secure the highest level of protection of patients' rights.

The most relevant eHealth services to the market, as regards mobility of the patient, can be recognised as: i) telemedicine, movement of health services without the physical movement of service providers (such as healthcare practitioners) and service recipients, ii) use of Electronic Health Records (via electronic storage and circulation of personal health data) to support the free movement of patients, iii) application of ICT tools in health treatment provided to patients who are abroad. The latter application is the least problematic as there are no foreseen major differences between Member States.

Nevertheless, the first of these applications – telemedicine and free movement of electronic health data – poses a series of open questions regarding: a clear definition of telemedicine services, harmonisation of diagnosis related groups that can be treated by telemedicine, accreditation of health professionals who provide telemedicine applications, a telemedicine providers' database, and reimbursement for telemedicine services. Greater legal certainty is needed as, in some circumstances, cross-border telemedicine falls under the existing regulations covering the free movement of patients and, in other situations, is covered by the rules regulating free movement of professionals or electronic commerce (e-Commerce Directive[25]).

To define a suitable legal and regulatory framework for eHealth services and goods, the following areas would need special attention:

1. Application of Personal Data Protection legislation to eHealth tools and services
2. Civil liability for defective goods and services
3. Jurisdictional certainty
4. Cross-border medical reimbursement
5. Patient mobility

If no action is taken on clarifying these five areas of legal uncertainty, there will be a stagnation in market development, and continued hindrance of both cross-border health provision and mobility of either services or personnel.

Insufficient availability of financial support

Closely related to issues of market fragmentation are issues concerning access to pump-priming funding for eHealth in an environment where health delivery is often funded through public monies.

Because there is not one owner of the various health systems (and therefore there is organisational fragmentation), it can be a challenge to introduce eHealth tools, such as disease management tools, into health systems so that the party responsible for making the investment reaps the benefits. Incentives and reimbursement schemes have to make sure that a sustainable financial plan is possible, and that all the relevant stakeholders contribute their part to the overall success. Organisationally and financially, eHealth should as much as possible address the complete care-cycle (from prevention to diagnosis, therapy/treatment and rehabilitation). That is an important way to avoid sub-optimisations in the clinical pathway.

Procurement issues

An important success factor for meeting the challenges of health and social care in a sustainable, cost-effective way is to address these through mid- to long-term strategic approaches that not only make use of the latest inventions and innovations but that also help steer the development of new solutions. The Commission has issued a Guide on dealing with innovative solutions in procurement[26] that provides examples of how the procurement of commercially available innovative solutions can be done.

Significant and sustainable improvements in the quality and efficiency of health and social care can also be obtained through the procurement of R&D services that can lead to solutions and technologies that do not yet exist and that will outperform the solutions available on the market. This will help accelerate the market uptake of innovations and open up new market and business opportunities for innovative companies, and could help lower the costs of care.

In addition, the eHealth market in Europe, like several other markets of innovations, suffers also from the fragmentation of public demand which in turn leads to a lack of exchangeability of products and services. The setting of different requirements by individual buyers at local, regional and national levels, the limited cooperation between procurers and between procurers and suppliers[27] to develop solutions applicable across different Member States are major barriers for the deployment of interoperable eHealth solutions across the Union. These are also barriers for the development of markets of sufficient scale to enable the quick uptake of innovations for the benefits of citizens and businesses.

Actions are needed to improve and coordinate procurement practices with regard to innovation so that industry does not provide only customer-individualised solutions resulting in technological delay and lack of economy of scale.

3 Strategic, economic and social **benefits**

eHealth can result in a number of strategic, economic, and social benefits for Europe. Strategically, a strong domestic market is a pre-condition for successful lead market strategies. Notably through effects of ageing societies in industrialised countries, but also due to population growth in some emerging and developing countries, there is an increased need for health services. Whether this translates into actual demand is of course a question of sufficient resources to pay for the goods and services that are required. For health the major source for such payments is social security schemes. Assuming that, in most developed countries that are affected by ageing, the expansion potential for the volume of these social security schemes is very limited since any increase impacts directly on competitiveness and export power, there are three remaining parameters that can affect provision: lowering coverage, decreasing quality, and containing costs. eHealth is one of the basic tools that can support coverage maintenance, raise quality levels, and contribute to long-term cost containment.

Better care can cost less. In economic terms, unit cost reduction/containment and higher quality through eHealth may limit effects arising from the transformation of healthcare delivery systems, alternatives and substitution opportunities, integration synergies, economies of scale strategies, re-engineering of care processes, improved quality and safety mechanisms, more complete and more accurate health information, and business intelligence. Measured against the major costs inherent in the health sector (such as the salaries of health professionals and staff, and the provision of pharmaceutical products), the costs of the major elements of eHealth are comparatively limited while the return on investment may be very high. The resulting gains in terms of increased efficiency and productivity are not only needed to respond to a higher demand for services of better quality at a contained unit cost, but also to face the wide range of other challenges that face healthcare systems today. These include increased health consumerism (a desire for 'more high tech and more high touch'); greater patient or carer individualism; diminishing family care potential; changing patterns of diseases; increasing complexity of treatments (and case mix index; increased healthcare professional workload (due to shorter lengths of patient stay in hospitals but higher patient turnover); shortages in qualified staff (such as physicians, nurses, radiologists); workforce instability and dissatisfaction; rising costs and increasing financial pressure; calls for more performance/profitability; and increased global competition (often termed 'health tourism'). Studies show that eHealth brings economic benefits and at the same time improves the quality of the health services provided.[28]

Maintaining current health service levels should be the minimum target for countries with a fully developed health system, but of course it is desirable to improve service levels whenever possible. For countries with less developed health systems, such improvements in service level are imperative. If this were possible by using eHealth solutions, then the positive effects of good health services on overall labour productivity[29], and thus competitiveness of the economies, can be sustained or expanded. This is the major contribution of eHealth to the renewed Lisbon agenda.

Adopting innovations on eHealth as a lead market, ideally by responding to market needs in terms of introducing standardisation and/or interoperability, can lead to technology advantages. Such technology advantages also serve the strategic objectives for research and development, because most eHealth products are comparatively research intensive. The external effects of such technology advantages are notably to be expected for the entire ICT sector and ICT infrastructures, both in the form of individual and of network externalities.

Technology advantages in strong lead markets foster export potentials for eHealth products, because large take-up in the lead market and proven performance reduce uncertainties for potential external buyers. Technology advantages in lead markets also mean innovation pressure. A strong demand for innovation
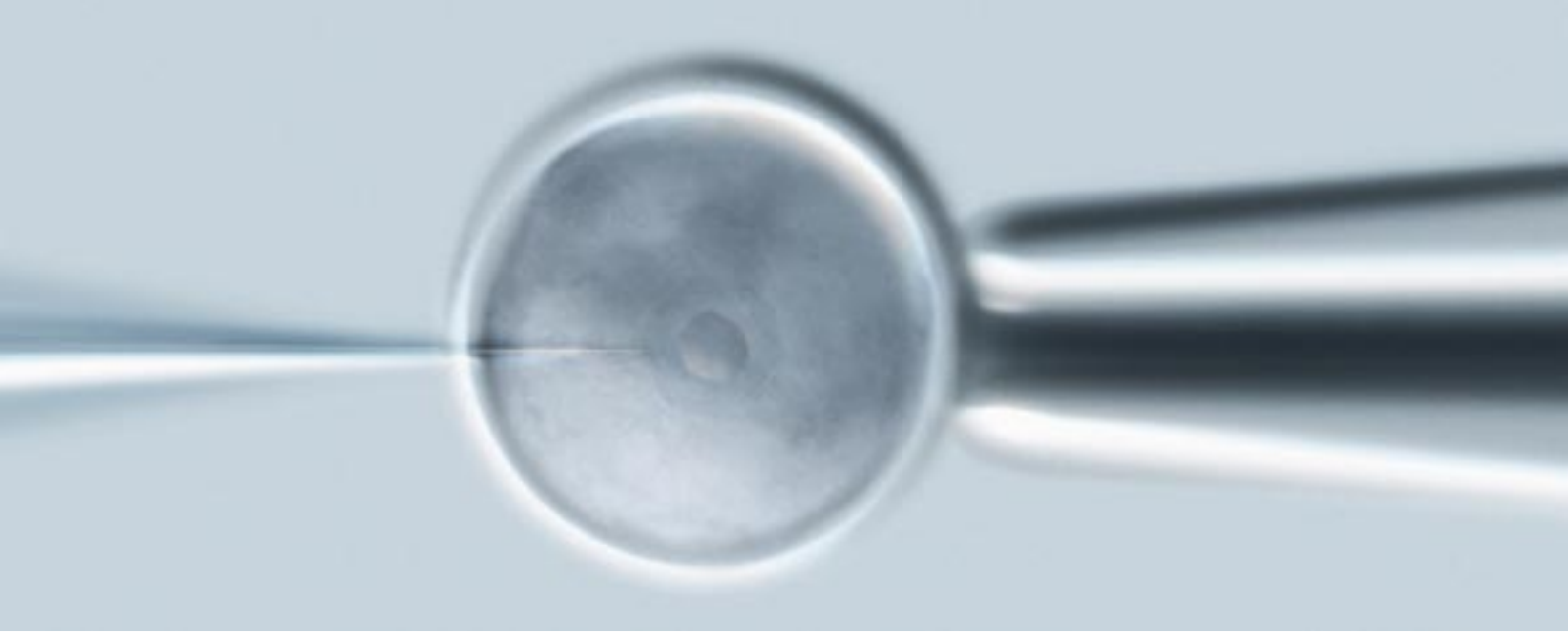
generally means strengthened competition. Customers of eHealth products in the lead market demand the highest quality at an affordable price. Such competition translates into more general competitive advantages. Global trends in eHealth show increasingly that advanced health-related technologies are being deployed in countries such as China, India, Japan, Singapore, Taiwan, Thailand, the United States, Vietnam[30] and others[31]. These trends require European industry to pay attention to cost-effective development and production in order to benefit from their competitive advantage and contribute to the European Commission's expressed aim of 'competing in the world'.[32]

The major social benefit of eHealth is that on average, health services can be offered at a lower price than when eHealth is not involved. Thus, there are positive effects for the affordability of health services and hence, a positive contribution to social cohesion. Improved accessibility to health services through eHealth, that contribute to territorial and social cohesion but also aid environmental and climate protection goals through reducing use of transportation, serves at the same time the specific needs of Europe's older inhabitants, for whom any frequent need for long-distance physical mobility may be difficult or uncomfortable. The territorial cohesion aspects of eHealth in terms of accessibility include further social cohesion effects, as migration patterns tend to concentrate better-off citizens in agglomerations, while comparatively poor people and elderly people remain behind in the rural areas. Provision of health services at a distance, through the use of eHealth, by serving patients in their place of residence and in their local area, can result in greater social cohesion, This series of social cohesion benefits is linked with improved integration, for which better information, including the 'informed patient', provides a major lever.

eHealth can also address employment difficulties as it allows health practitioners and institutions in parts of the world where there is a shortage of certain specialised services to receive remote assistance. Health practices that face a shortage in staff on a permanent or even temporary basis (due to holiday leave, sickness, and postgraduate training) are ideal candidates.[33]

4 Removing barriers

to eHealth market development

In the context of the creation of a market for innovative eHealth products and services, the following specificities - and particularly the involvement of public authorities - should be taken into account appropriately:

- The dominant involvement of public authorities in structuring, managing, financing, organising and delivering healthcare services, including eHealth solutions, and the specific legal and regulatory provisions which are at the basis of an effective healthcare system, make healthcare a special market.
- The organisation, financing and delivery of health and medical services are the domestic responsibilities of Member States[34].
- The structuring, management, and financing of Member States' health systems and services differ considerably.
- The dominant source of healthcare expenditure in the European Union is procurement[35]. The procurers of eHealth systems, such as health information systems, electronic health records, and telemedicine systems, are mainly public organisations and bodies, or bodies financed through public funding.
- The achievement of healthcare modernisation objectives requires the active engagement of public authorities and provision of very significant amounts of additional resources to enable this change process. Public authorities are understandably prudent in the administration of important resources; they are not keen to take risks. eHealth offers a number of opportunities to radically change the delivery of healthcare to the benefit of all concerned, however a discussion on (strong) outcome at public authority level is necessary in order to move away from administrative and cost-saving discussions.

A general discussion on the creation of a paradigm shift in perception and presentation to these obstacles and barriers follows, before a list of the four major fundamental steps in creating a market for innovative eHealth products and services is presented.

The Aho Report pointed out the need in Europe to shift from "a culture traditionally adverse to risks and to changes, to a culture centred on innovation, which by definition it includes an important element of risks". It identified the creation of an innovative Europe as a core objective to ensuring a prosperous future for European citizens. As suggested by the Report, besides achieving a more risk-oriented approach, an additional paradigm shift is essential to create a stronger market for innovative eHealth products.

This paradigm shift is required to ensure that policy-makers no longer consider healthcare as a public sector funding cost but rather as a longer-term social and economic investment. The impact of the health sector on everyday life and economy has to be seen from a broader angle. There is evidence that investing in health brings substantial benefits for the economy. According to the World Health Organisation, increasing life expectancy at birth by 10% increases the economic growth rate by 0.35% a year. On the other hand, ill health is a heavy financial burden illustrated as 50% of the growth differential between rich and poor countries is due to ill-health and life expectancy[36]. The European Commission's recent health economy report[37] provides important empirical evidence that supports the direction of this argument, by describing the impact of health in the economy and the rationale for investing in health. Once it has been accepted that to invest in health provides an important element to support Europe's economy, the need to focus investments on tools, such as eHealth, which improve the organisation and quality of healthcare will be an obvious consequence.

There is a need to change the way eHealth is perceived. The old perspective was of eHealth "just another expense" in a healthcare budget line for which there is not enough funding. The new vision should instead recognise eHealth as how to do healthcare in 21st century, as "the tool for increased productivity and quality of care"[38], as a provider

of information to authorities and payers, as well as an opportunity for more effective forms of management.

Increased productivity and savings, which are very important benchmarks for health authorities, have also been demonstrated and need to receive more attention on the part of policy-makers[39]. Hence, this paradigm shift in perception and presentation needs to be supported by increasingly hard, empirical evidence acquired through evaluation, assessment, and benchmarking methods and procedures. The required organisational changes should also be supported by appropriate training procedures and operational guidelines. Only if all operational levels, including investment decisions, procurement practices, and legal and regulatory frameworks, support this shift can innovative eHealth solutions be implemented and sustainable in the long-term.

The Commission will continue to support healthcare authorities at both national and regional levels in the Member States regarding the promotion of these paradigms: Vision (moving eHealth from a connecting systems approach to a connecting people approach), data on the effectiveness of eHealth, suggestions for action, and dissemination of good examples.[40]

The challenge is to make sure that such types of activities reach the appropriate target audiences. eHealth is an area in which responsibilities are either held by Health Ministries uniquely or are sometimes shared between Health Ministries and Technology, Trade or Innovation Ministries. In addition, in several Member States there is a clear trend to decentralise the provision of healthcare services and/or create a greater role for private operators. This can create difficulties in ensuring that messages on added value and the cost-effectiveness of innovative eHealth solutions are conveyed to the correct target audience. National health authorities and stakeholders' involvement can provide important support in facilitating these processes and overcoming these challenges. Certainly more attentive and thoughtful work still needs to be undertaken to ascertain what marketing and public relations' mechanisms, methods, procedures, and messages are required. Upcoming events and activities, including conferences, could gather such information in a systematic and structured manner. Information could and should be gathered equally from national and regional health authorities and their competence centres, from stakeholders in areas of private healthcare, and citizens themselves.

The following specific activities have been identified as the four necessary steps to take in order to create a market for innovative eHealth products and services in response to the respective obstacles.

ADDRESSING MARKET FRAGMENTATION AND LACK OF INTEROPERABILITY

ACCELERATING THE TAKE-UP OF EU-WIDE EHEALTH SOLUTIONS THROUGH PILOT ACTIONS UNDER THE COMPETITIVENESS AND INNOVATION PROGRAMME

SUPPORTING HEALTHCARE AUTHORITIES IN THE PROMOTION OF PARADIGM SHIFTS, INCLUDING IN PARTICULAR THE INTRODUCTION OF EHEALTH SCORECARDS

ADDRESSING LACK OF INTEROPERABILITY BETWEEN SYSTEMS

A4. ADDRESSING THE NEED FOR CERTIFICATION

EXPLORING THE LACK OF LEGAL CERTAINTY

APPLICATION OF PERSONAL DATA PROTECTION LEGISLATION IN PRACTICE TO EHEALTH TOOLS AND SERVICES

CIVIL LIABILITY FOR DEFECTIVE EHEALTH GOODS AND SERVICES

JURISDICTIONAL CERTAINTY

CROSS-BORDER MEDICAL REIMBURSEMENT

SUPPORTING PATIENT MOBILITY

AVAILABILITY OF FINANCE

ADDRESSING THE INSUFFICIENT AVAILABILITY OF FINANCIAL SUPPORT

PROCUREMENT ISSUES

ADDRESSING THE PROCUREMENT OF INNOVATIVE SOLUTIONS

Addressing market fragmentation and lack of interoperability

The new Competitiveness and Innovation Programme brings together a range of European actions into a single comprehensive programme with a clear objective: Increasing European competitiveness and innovation. The ICT Policy Support Programme (which forms a part of the Competitiveness and Innovation Programme) will support pilot actions using innovative ICT-based services of public interest. eHealth has been identified as one area of priority for this Programme.

By definition, healthcare is an extremely fluid sector. Doctors, hospitals, insurance companies, and patients are subject to a series of regulatory changes, advances in treatment, procedural changes, and mergers or acquisitions. Each change requires an adaptation of information systems, and each adaptation potentially impacts some or all systems. Point-to-point integration quickly becomes costly and complex to maintain, and results in delays, inaccuracies, large amounts of paperwork, and frustration for healthcare providers and consumers alike. The establishment of an information infrastructure has many challenges, including in particular the challenge for interoperability between health ICT systems and applications to enable them to 'speak the same language'.

The priority of Calls for Proposals in 2007 is financial support to a large-scale deployment pilot in patient summary exchange. The pilot will implement and demonstrate interoperability by creating service operations between cooperating Member States. This includes the interoperability of patient summaries including an emergency data set, and ePrescription. The large-scale pilots should enable the deployment of interoperable eHealth solutions that could start in a subset of Member States, involve the revision of a common specification for eHealth interoperability at a European level and, finally, could outline the relevant barriers to eHealth implementation and the need for additional support actions to facilitate eHealth interoperability.

SUPPORTING HEALTHCARE AUTHORITIES IN THE PROMOTION OF PARADIGM SHIFTS, INCLUDING IN PARTICULAR THE INTRODUCTION OF EHEALTH SCORECARDS

There is a clear lack of up-to-date and complete information on eHealth services provided by European industries and Member States. An Innovation Scorecard approach, complete with a set of indicators, should be proposed in agreement with representative stakeholders to measure eHealth performance in the eHealth Market.[41] The idea is to establish indicators which should be measured in the same way across all the Member States and thus serve as a benchmarking tool that could be used to compare one country against another. Its purpose would be to enable Member States to see for themselves their strengths and weaknesses and thus help them in formulating policies and programmes. High scoring Member States may increasingly become sources of good practice as users of the scorecard look to adopt what has worked elsewhere. This approach is thus a starting point for discussion and action, a factual foundation for future measures. The richness of detail enables policy-makers and opinion-formers to use it as a tool in order to identify priorities, articulate strategies, and to measure the success of those strategies.

ADDRESSING LACK OF INTEROPERABILITY BETWEEN SYSTEMS

An initiative that focuses on reducing market fragmentation and increasing eHealth interoperability could reinforce the existing cooperation between Member States by setting clear guidelines to implement targets for eHealth interoperability, such as expanded use of electronic health records, online health services, e-prescribing, e-pharmacy, standardisation efforts, and all the relevant supporting good practices.

The Commission's report on 'Connected Health' (September 2006)[42], has already outlined the key priority issues which must be pursued to achieve the goals of collaborative and continuous care provided with high-quality and appropriate cost in Europe.

Further to this, a Recommendation from the European Commission on eHealth interoperability is due to be published in November 2007. The directions and content of the Recommendation aim to include:

- Dialogue: Start a dialogue on achieving a European health information space by 2015.
- Agreement and engagement: Indicate on what principles there need to be broad agreement and engagement in order to reach shared and interoperable eHealth systems by 2015.
- eHealth supporting health: Show that - to provide Europeans with the appropriate kinds and level of healthcare - supporting information and communication technologies is needed.
- Framework: Form a 'framework' enabling all Member States to participate and identify an appropriate role.
- Equitable basis: Act as the basis for an equitable level of understanding and implementation of the principles involved.
- Interoperability: Focus on interoperability between health information shared among different healthcare systems, and based on a limited range of applications in current existence and use in different Member States.

- Semantic Interoperability: Improve semantic interoperability by adopting a common terminology framework.

The Recommendation will be rigorously followed up in the i2010 sub-group on eHealth, its attached expert group on eHealth interoperability and various stakeholder groups, and will be a major influence on the eHealth part of the Competitiveness and Innovation Programme of 2008 and 2009. A focused session at the World of Health IT Conference in Vienna (October 2007) is foreseen to follow up on the Recommendation in a stakeholder arena.

Standardisation is an integral part of the European Union's policies to increase competitiveness of enterprises and to remove barriers to trade.[43] In the eHealth area, the 2005 Report from the European Committee for Standardization (Information Society Standardisation System eHealth Standardisation Focus Group, March 14, 2005), emphasises that health information standards are essential to achieving the goals of eHealth in Europe. The report recommends the creation of an interoperability platform, which, among other tasks, should establish a Europe-wide view on the requirements for eHealth standardisation and its implementation in collaboration with standardisation organisations based on input from relevant stakeholders'.

The report proposes that semantic aspects and technical means to eHealth interoperability also have to be harmonised through setting and enforcing voluntary standards. Standards have to be defined at European or - even better - at international level with the participation of relevant stakeholders. To guarantee semantic interoperability, systems and solutions have to be designed properly based on a defined architecture. This is especially important for shared applications such as electronic health record systems. Furthermore, content and its representation has to be agreed upon. Semantic and technical interoperability can be enabled by standardising technical interfaces, protocols, messages and documents; so the business processes involved in such a context can be harmonised by defining clinical procedures and pathways.

Many forms of standards could be appropriate to eHealth; standards for devices, protocols, messages, documents, processes, architecture, design and modelling, as well as standards for infrastructure and infrastructural services with specific emphasis on safety, security and privacy services. Furthermore, standards for specifications, knowledge representation, terminologies and ontologies can be deployed for shared care through a voluntary, collaborative process that involves all the relevant stakeholders.

In March 2007, the three European Standards Organisations (CEN, CENELEC and ETSI) received a Standardisation mandate in the field of ICT, applied to the domain of eHealth.[44] The goal is to list existing relevant standards and technical reports, and to agree on implementable standards, technical reports, guidelines and methods.

ADDRESSING THE NEED FOR CERTIFICATION

eHealth interoperability requires a common process for analysis, specification, implementation and deployment of conceptual models, common concepts, and a framework architecture and its prioritised solutions for infrastructure elements and services. In this context, legal and other regulatory policies, collaborative business views, a common understanding of process, information and concepts based on reference models and terminologies or ontologies, have to be brought together. The process for benchmarking, evaluating, and labelling the conformance to these requirements performed by a body that is duly authorised and recognised is called certification.

Specifications and protocols used should preferably be standardised at an international level or at least be mutually agreed among the various parties involved. Certification services can be implemented in a centralised or – even better – in a hierarchically decentralised way. Clear specifications must be established to allow suppliers to submit adequate proof. Today, there is little or no experience with certification at the high (semantic) levels that are needed in the eHealth field. Current practical experience (for example, with DICOM[45] or with Integrating the Healthcare Enterprise) shows that conformance claims by industry, together with voluntary testing sessions and testing tools in the public domain, are, however, very effective and efficient methods of providing certification.

Based on work in the Member States and on the outcomes of the European project Q-REC[46], as well on a validation process initiated with the implementation authorities or bodies, guidelines for certification of eHealth applications should be prepared. The goal will be to create conformance-testing methods and processes (an example is the Integrating the Healthcare Enterprise annual -a-thons) where components, applications, and tools can be evaluated for their adherence to standard profiles. Software and hardware testing processes that identify incorporation of and compliance with these profiles should assist vendors and purchasers of software to direct their resources toward those eHealth systems that offer interoperability.

Exploring the lack of legal certainty

A top priority is to restart the revision process of existing regulatory framework in the area of eHealth by systematic screening and impact assessment, which should not be merely limited to the eHealth domain. To this purpose, the Commission services will also examine carefully the recommendations of the recently-delivered Legally eHealth study (June 2007), in order to assess whether additional regulatory provisions are necessary or whether current provisions are sufficient to ensure legal and regulatory certainty.

Following the findings of this legal analysis, the Commission will explore possibilities for a legal initiative that could encourage Member States to support actively the introduction and use of eHealth and telemedicine[47]. This initiative will run in parallel with the ongoing Community action on health services which aims to develop a Community framework for safe, high quality and efficient health services, by reinforcing cooperation between Member States and providing certainty over the application of Community law. eHealth, as an integral part of cross-border care, has also been addressed in the 'Open Consultation Regarding Community Action on Health Services',[48] which has provided valuable observations.

It should also be noted that within the ICT theme of the Seventh EU Research Framework Programme (FP7), security and privacy issues have been identified as a key area to be addressed in research and development projects co-financed by the European Commission. In addition to traditional security and privacy issues, the proposed research solutions should address the specific implications related to the use of genetic data such as genetic predispositions.

APPLICATION OF PERSONAL DATA PROTECTION LEGISLATION IN PRACTICE TO EHEALTH TOOLS AND SERVICES

The fundamental right to the protection of personal data is based on Article 8 of the European Convention for the Protection of Human Rights and Fundamental Freedoms and on Article 8 of the EU Charter of Fundamental Rights. More precise rules are in particular laid down in the EC Data Protection Directive 95/46/EC[49] and in Directive 2002/58/EC on privacy and electronic communications[50], and in the national laws of the Member States implementing these Directives.

eHealth by definition requires the sharing of patient identifiable data when and where necessary. Users of eHealth applications therefore have to ensure that they respect the fundamentals rights of the individuals concerned, and comply with the legal obligations for the protection of personal data of the patients. When the processing of such personal data relates to a person's health, processing is particularly sensitive and therefore requires special protection. In the eHealth context, the processing of personal data in health systems across Member States may vary due to their national specifics and the diverse transposition and implementation of the Directive[51].

It is therefore important to consider whether the EU should adopt special interpretative guidelines to the provisions of Directive 95/46/EC, or other actions to promote proper implementation and improved enforcement of the Directive so that eHealth-related stakeholders are made more aware of the rules for personal data processing in the field of eHealth. In particular, the Article 29 Working Party, that brings together national data protection supervisory authorities, alongside the Member States representatives in the i2010 sub-group on eHealth, could provide a key element for insight into these aspects of data protection in the health area, in particular in seeking greater EU-wide enforcement.[52] The European Commission will also pursue proper implementation of the provisions of Directive 95/46/EC at national and international levels.

CIVIL LIABILITY FOR DEFECTIVE GOODS AND SERVICES

Liability for the quality and safety of eHealth goods is covered reasonably well by the general legislation in Europe on product safety and consumer protection. However, eHealth products are still rather new and much uncertainty exists about who is liable for what and how liability is split among different service providers in the eHealth continuum, especially when this uncertainty relates to cross border healthcare beyond that already provided by international private law. In this context, based on the Directive 374/1985/EEC of 25 July 1985 on liability for defective products, efficient protection for civil liability against defective goods and services must meet the objectives of spreading fairly the risks inherent in a modern high-technology society, protecting consumers' health, stimulating innovation, securing undistorted competition, and facilitating trade. Connection to the law of the place where the person sustaining the damage has his or her habitual residence, together with a 'foreseeability clause', is a balanced solution in regard to these objectives. To ensure consumer rights, national surveillance authorities have been established to monitor product safety and to take appropriate measures. The European information system (RAPEX) was put in place to impose collaboration between distributors, producers and the national authorities but also between Member States and the European Commission. Accordingly, the Commission's permanent task remains to enhance better enforcement of consumer protection by the Member States and information dissemination for citizens to use the existing institutional framework also for eHealth products, for example, also through ECC-NET and SOLVIT.

Most of the contractual relationships in the health sector are regulated by contracts between the parties concerned. A number of legislative instruments at the EU level have already been adopted to ensure that parties to such contracts can know in advance under which jurisdiction any eventual dispute will be solved; namely, the Brussels I Regulation concerning jurisdiction and the recognition and enforcement of judgements in civil and commercial matters and the 1980 Rome Convention on the law applicable to contractual obligations (Rome I). Furthermore a number of regulations have been adopted covering issues such as insolvency proceedings, the service of documents in cross-border cases, and the taking of evidence in civil and commercial matters. A draft Regulation on the law applicable to non contractual obligations (Rome II) is currently being discussed in the Council which the intention of modernising and simplifying the liability legislation and strengthening the protection of individuals such as consumers, patients, and employed persons.

Besides existing legal remedies, there are many practical suggestions, such as putting in place alternative dispute resolution systems for cross-border care (perhaps building on existing networks such as SOLVIT), requiring mandatory insurance for healthcare providers, or establishing a Europe-wide no-fault compensation system.

Much could be done to enhance the take-up of eHealth tools and services across EU borders, if the legal provisions outlined above were more widely and understandably communicated to the whole health community.

CROSS-BORDER MEDICAL REIMBURSEMENT

Despite the significant progress achieved in the use of ICT in health area, the reimbursement for cross-border services in eHealth is not regulated at the EU level. The mechanism used for cross-border care reimbursement in the EU is based on Regulations on coordination of social security systems[53] and on the Internal Market rules concerning the free provision of services which have been clarified by the European Court of Justice[54]. Although the existing regulations provide a well-established tool that has ensured social protection for workers, tourists and patients travelling within the EU, the system needs improvement in order to exploit the great potential for eHealth applications for the enhancement of safer, more efficient cross-border care in which, in many cases, neither patient nor practitioner would need to move physical location. Every effort should therefore be made to ensure that the potential revision of legal provisions around patient mobility is fully aligned with the use of eHealth goods and services to deliver healthcare across borders.

The reasons why considerable potential for eHealth applications could be foreseen, in so far as they can enable healthcare provision at-site rather than involving either professional or patient mobility, include that they may provide solutions to the following four difficulties:

- The difficulty in identifying a provider that accepts the European Health Insurance Card (EHIC).
- Not all healthcare providers accept the EHIC despite their obligation to do so. Such non-acceptance of the card can therefore lead to direct payment for the services by the patient him- or herself, and reimbursement then often refused after the patient returns home.
- Reimbursement procedures can be administratively burdensome for providers, and lead to delays and shortfalls in reimbursement.

SUPPORTING PATIENT MOBILITY

Both existing and emerging disparities in Member States' legislation and case-law concerning healthcare prevent the smooth functioning of the internal market, in particular by impairing the development of cross-border services and producing distortions of competition.

The following actions are therefore required:

- Promoting the use of cards in the healthcare sector. Adoption of implementation of an electronic health insurance card by 2008.
- Empowering citizens by giving them clear and transparent information on their patients' rights. Establishing an electronic database of healthcare providers (such as general practitioners, specialists, dentists, and pharmacists). Such a provider database with detailed information would also be desirable for citizens who seek treatment in their own Member State and could be available through existing national healthcare information points.
- In addition, providing a European central information point should help citizens to improve access to information related to cross-border healthcare and should provide another possibility to seek treatment in their home Member States. A possibility to use the existing EU health portal to that purpose should be examined.
- Establish a common electronic EU diagnostic system which codifies diagnoses and treatments in order to identify the appropriate reimbursement level and which would incorporate the fact that some health systems now bill for time (hours/days), others for frequency of visits, and yet others for diagnosis related groups – an approach which is becoming more frequent.

Addressing the insufficient availability of financial support

The Aho Report argued that the proportion of EU structural funds dedicated to research and innovation should be elevated from the current 6% to 20%. The European Union structural funds could provide major opportunities to support deployment of eHealth solutions and thus contribute to the developments of an eHealth market. The recently-revised European Union policies in regional development offer more possibilities than previously. The new Cohesion policy 2007-13 includes an unprecedented focus on health-related items and supports the promotion of the information society for all – including eHealth initiatives.

In this regard, the European Commission has launched a study which will assess ways and means of financing eHealth and boosting investment in this field.[55] At the same time, the Commission is organising training workshops particularly for new Member States, accession countries, and other countries which may at a later stage become interested in joining the European Union on how to seek financing for their healthcare systems and services, and will include similar information on eHealth[56].

In this context, it is worth noting that to respond to the growing challenge and the financial constraints healthcare systems are facing, one of the approaches adopted by some Member States is to provide a greater role to private operators as healthcare providers and payers. This also reflects a general trend in the reform of public services and the enhanced use of Public Private Partnerships.

Finally, the Commission will streamline its business support and information networks. This will encourage and facilitate the take-up of new ideas and their transformation into marketable products and services, especially by SMEs. In particular it will help to ensure that the Innovation Relay Centres and Euro Info Centres provide top-class business services to SMEs.[57]

Addressing the procurement of innovative solutions

Where procurement for innovation is inherently a risky enterprise and most public bodies in their capacity as contracting authorities are by nature risk-averse, there is a need to raise awareness that these risks can be managed such that the benefits of the solution outweigh the risks. This would improve the chances of having procurement of products and services which are better fit for purpose. This covers both the procurement of innovative products and services that are already commercially available and procurement of R&D services providing solutions that outperform those available on the market. The procurement of R&D services may or may not involve risk-benefit sharing.

Networking and cooperation between public procurers[58] in the development process of new solutions could lead to better interoperability and exchangeability in the public sector and thereby better productivity and lower costs for the procurers, on one hand, and economies of scale incentivising companies to compete on the other hand.

The Commission plans to invite relevant stakeholders to further consider the possibilities to create and support networks that foster cooperation and sharing of best practices among procurers in specific areas of common interest. These could include: Cooperation during the procurement phase and openness to innovation. An effort will also be made to encourage involvement of eHealth authorities in CIP and FP7 calls for proposals.

5 Elements of validation by stakeholders

In support of the preparation of this report on the Lead Market Initiative as it applies to eHealth, widespread consultation of stakeholders was carried out. The key questions that were asked both in face-to-face meetings and in a dedicated questionnaire were as follows:

1. What are the emerging eHealth market segments?
2. What are European industry and technology strengths for the eHealth market? What are the industry commitments?
3. What do you consider to be the main obstacles to the development and growth of the eHealth market? What do you consider to be the top 3 challenges for EU-wide deployment of eHealth services and solutions? How can the growth of the development of the eHealth market be accelerated?

What could/should the public authorities (regional, national, EU) do to weaken/remove these obstacles?
What would be the outcome if no action is taken to remove these obstacles?

The following groups were consulted in face-to-face meetings:
• i2010 sub-group on eHealth. Representatives from Ministries of 32 European States were present at the meeting in Berlin on 16 April 2007.

The group welcomed the initiative and emphasised in particular the importance of coordination across different public authorities to achieve effective and efficient results. The group consented to the two eHealth stakeholders' groups having the mandate to provide input to the draft document.

• eHealth Stakeholders' Groups reporting to the i2010 sub-group on eHealth
  o Industry representatives, including:
• The Continua Health Alliance (a consortium of 100 companies)

• COCIR (the European Coordination Committee of the Radiological, Electromedical and Healthcare-IT Industry, a consortium of 30 enterprises and national industry associations)
• IHE (Integrating the Healthcare Enterprise)
• EHTEL (European Health Telematics Association).

The industry stakeholders' group "strongly supported" the involvement of eHealth in the Lead Market Initiative and made clear recommendations regarding obstacles and solutions that were classified in the following fields:

• Political: support the healthcare authorities with measures to combat the fragmentation in the eHealth market, encourage the use of Structural Funds, develop indicators, provide data on effectiveness of eHealth;
• Organisational: disseminate good practices in the Member States, initiate studies which show how to overcome the organisational fragmentation in providing eHealth solutions;
• Financial: initiate studies and reports to show the benefits of a financial model that comprises the complete care cycle, increase funding in the direction of support for deployment;
• Application/workflow: stimulate the engagement of the professional organisations of healthcare providers, clinicians and patients in developing eHealth solutions;
• Clinical Evidence: provide seed funding for realistic eHealth applications to explore in more detail the benefits of eHealth;
• Technological, Standards, Regulations: address the challenges in the area of semantic interoperability between healthcare systems in large-scale pilot projects for realistic applications, stimulate the use of one medical terminology standard in Europe, with translations in national languages, use the experience from certification the healthcare industry to accept self-certification also in the domain of interoperability

and eHealth, support standardisation initiatives such as Integrating the Healthcare Enterprise and Continua;

- Legal: develop a legal framework for cross-border healthcare services, including registration, responsibilities, liability legislation, and the consequences of cross-border communication of medical data, stimulate the development a legal basis for telehealth, even within one country, provide a harmonized interpretation of the data protection law for personal medical information, consider whether a high-level social framework legislation such as "dependency law" can be used in all Member States;
- Procurement: educate procurers of IT systems for eHealth, topics to cover would include: governance during the procurement phase, innovative procurement schemes with "pay-per-patient" or "pay-per-service" models, partnering with the IT solution provider in order to create a common win/win, and openness to innovation;
- Education: provide seminars and conferences to educate various audiences about how to improve healthcare and social care through the use of ICT and about how the Commission can support local projects, with funds or otherwise
- Cultural/emotional: Take into account cultural and emotional aspects when evaluating large pilot projects.

The industry stakeholders provided a first input during its meeting on 23 April 2007 and further input in reaction to the first draft of the Commission Task Force's report, making suggestions in particular to make the report more comprehensible by people not familiar with healthcare and the role of eHealth and strengthening some of the arguments through additional statistics.

- Users representatives Stakeholders' Group, including:
- AIM Association internationale de la Mutualité
- CPME (Comité Permanent des Médecins Européens) /Standing Committee of European Doctors

- EHMA (European Health Management Association)
- HOPE (European Hospital and Healthcare Federation)
- PGEU Pharmaceutical Group of the European Union
- Standing Committee of Nurses of the European Union (EFN, formerly PCN)
- European Union of Medical Specialists/Union Européenne des Médecins Spécialistes
- WMA (The World Medical Association)
- EHTEL (European Health Telematics Association)

The eHealth users' stakeholder group provided useful feedback in response to the initial consultation at a meeting on 22 March 2007. The user stakeholders also provided feedback following the first draft of the report. The group members insisted on including a focus on health professionals and on patients in the development of the eHealth Lead Market Initiative.

- AmCham EU (represented by HP and Oracle)

These stakeholders welcomed the initiative at the EU/US eHealth workshop in May 2007. Useful input was provided regarding standardisation, incentivisation and certification issues.

A variety of other approaches were also made to optimise stakeholder feedback.

- Other groups consulted by DG SANCO were:
  - o Interservice Group on Health Strategy
  - o Health Systems Working Party
  - o Network of Competent Authorities.

- The questionnaire was circulated at the following conferences:
  - o Organised with support by DG INFSO H1
- eHealth Conference 2007 in Berlin, +/-1000 policy oriented attendees
- Med-e-Tel 2007 conference in Luxembourg

- Telehealth 2007 conference in Hannover.

- The questionnaire was circulated to CATEL a predominantly French network of more than 5500 contacts concerned by telemedicine (including practitioners, firms, associations, and institutions), and 400 active members.

- The questionnaire was widely circulated via email, and particularly received responses from members of, for example the BRT (Brussels Round Table for Telecom Operators) and EICTA (European Industry Association for Information Systems, Communication Technologies and Consumer Electronics).

- Contact has been established with various ICT European Technology Platforms (such as Artemis, EPoSS, IME, eMobility, NanoMedicine, and NESSI), in addition to the initial consultation that was already circulated in July 2006.

6 Roadmap for Implementation of eHealth Task Force Lead Market Initiative Policy Recommendations

Aims	Targets	Measurable actions
A. Reduce market fragmentation and lack of interoperability	A1. Accelerate uptake of EU-wide eHealth solutions	• Launch pilot actions under the CIP
	A2. Support healthcare authorities in promoting paradigm shifts	• Introduce eHealth Innovation Scorecards/Benchmarking to monitor eHealth performance in Member States (MS) and facilitate learnings • Coordination actions including exchange of best practices at i2010 sub-group meetings and annual eHealth conferences
	A3. Enhance eHealth interoperability	• Adopt Recommendation on eHealth interoperability • Favour the application of Recommendation on eHealth interoperability by enhancing cooperation between MS to build coherence in their health systems • Define required standards, establish review committee to identify focus areas
	A4. Provide adequate certification	• Issue guidelines for certification of eHealth applications • form expert group to encourage MS to establish a coordinated work program
B. Improve legal certainty and consumer acceptance	B1. Improve legal certainty	• Screen existing EU legislation related to eHealth and provide clarification and guidance for applying the legal framework for eHealth products and services • Analyse possibilities for adoption of a legal initiative for eHealth and telemedicine
	B2. Ensure adequate protection of personal data in eHealth systems	• Adopt initiative to enforce Personal Data Protection legislation for products and services
	B3. Enhance enforcement of consumer protection legislation by Member States for eHealth products	• Promote knowledge and information dissemination on safe and secure eHealth products and use of existing infrastructure to protect consumers – networks, best practice repositories, hotlines
	B4. Improve cross-border reimbursement	• Introduce the Electronic Health Insurance Card • Improve legal clarity regarding medical reimbursement based on recommendations from the Health Services Initiative
	B5. Support Patient Mobility	• Provide citizens with relevant and up-to-date information on cross-border health services
C. Optimise funding opportunities	C1. Mobilise public and private financing	• Provide guidance on financing from such funding mechanisms as the EU structural funds and European Investment Bank initiatives specific to eHealth domain – workshops, networks etc • Strengthen R&D on ICT for Health in FP7 and in Member States programmes • Strengthen cooperation between national and community R&D testing and pilots, involve users in RTD actions
D. Improve Procurement	D1. Facilitate expression of public demand through more innovation-friendly procurement activities	• Promote networking and cooperation among public procurers in the development process of new solutions • Associate procurers in consultation process for CIP and FP7 calls for proposals

• Many of these actions could be focused on "Telemedicine and Personal Health systems (cf. category 5 in section 1) - fostering innovation in chronic disease management and contributing to healthier and longer living", as defined in the Commission's APS 2008. In particular, home health monitoring is the telemedicine application with the greatest potential for financial and clinical impact[59]. It is characterised by high patient-readiness but continuing low vendor maturity and an unclear legal framework (liability, reimbursement etc.) that negatively affects the business model.

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2. The market definition was proposed by the eHealth Industry Stakeholders Group, reporting to the i2010 Sub-group on eHealth. The Stakeholders group includes the following representative organisations: COCIR (European Coordination Committee of the Radiological, Electromedical and Healthcare-IT Industry.), IHE (Integrating the Healthcare Enterprise), EHTEL (European Health Telematics Association) and the Continua Health Alliance.

3. Price, Waterhouse, Coopers study, HealthCast 2020: Creating a Sustainable Future, 2006

4. Health Information Network Europe (HINE) report 2006 – European eHealth forecast

5. We would like to distinguish between medical and health services whose expenses are normally covered by social security and wellness services such as spas and fitness centres which exhibits the normal consumer driven market.

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21. See in particular case C-148/02 Carlos Garcia Avello [2003] nyr, paragraphs 23 – 27, referring to C-336/94 Dafeki [1997] ECR I-6761, paragraphs 16 to 20; and C-135/99 Elsen [2000] ECR I-10409, paragraph 33.

22. Summary report of the responses to the consultation regarding "Community action on health services" (SEC (2006) 1195/4 of 26 September 2006).

23. The Directive on Services on Internal market was adopted in December 2006 by the European Parliament shall be transposed by Member States by 2009.

24. Directive 2000/31/EC of the European Parliament and of the Council of 8 June 2000 on certain legal aspects of information society services, in particular electronic commerce, in the Internal Market, OJ L 178, 17. 7. 2000, p. 1-16.

25. SEC(2007) 280, 23.2.2007, Commission Staff Working Document, Guide on dealing with innovative solutions in public procurement – 10 elements of good practice

26. consideration 8 of directive 2004/18/EC states that contracting authorities may seek or accept advice which may be used in the preparation of the specifications provided, however, that such advice does not have the effect of precluding competition.

27. "eHealth is worth it" report of the study Health Impact http://www.ehealth-impact.org/

28. European Commission: The contribution of health to the economy in the European Union, Luxembourg, Office for Official Publications of the European Communities, 2005.

29. See http://pacifichealthsummit.org/initiatives/hitlab/casestudies.aspx for case studies from these countries

30. See the WHO survey "Building Foundations for eHealth" (http://www.who.int/kms/initiatives/ehealth/en/) which summarises the position for a number of countries around the world.

31. See COM (2006) 567 'Global Europe: competing in the world: A contribution to the EU's Growth and Jobs Strategy

32. Eurad Consult, a company based in Belgium, regularly provides Teleradiology services in UK and Holland, balancing the surplus of qualified radiologists in Belgium with the shortage in the other two countries. For details, see Eurad's response to the Open Consultation Regarding Community action on health services, launched by the Commission of the European Communities - The concrete case of teleradiology services - Eurad

33. Article 152 of the Treaty of the European Union

34. OECD Indicators, 2005 www.oecd.org

35. Macroeconomics and health: investing in health for economic development", Report on the Commission on Macro-economics and health, Jeffrey D. Sachs, WHO, 20 December 2001

36. The contribution of health to the economy in the European Union, EC- DG SANCO

37. ICT for Health and i2010 www.ec.europa.eu/information_society/ehealth

38. "eHealth is worth it" report of the study Health Impact http://www.ehealth-impact.org/

39. A recent example is the eHealth ERA report – "Towards the Establishment of a European eHealth Research Area", eHealth priorities and strategies in European countries.

40. Such a policy recommendation has already been made regarding the medical device sector in Europe by the study prepared for DG Enterprise of the European Commission in

41. July 2005 by Fabio Pammolli and colleagues from CERM and the University of Florence, Medical Devices Competitiveness And Impact On Public Health Expenditure: "Member States and the European Commission should promote and establish a coherent statistical framework for the analysis of the competitiveness and innovativeness of the medical device sector in Europe"

42. Connected Health - Quality and Safety for European Citizens, Report of the Unit ICT for Health in collaboration with the i2010 sub-group on e-health and the eHealth stakeholders' group, September 2006

43. This position was confirmed by the European Parliament in 1999 and by the Council both in its Resolution of October 28, 1999 and its Conclusions of March 1, 2002 on the role of standardisation in Europe. At the same time, the Council invited the Commission to review the objectives, scope and needs

of European standardisation policy. The results of this analysis of standardisation policy were presented in the 2004 Communication on The Role of European standardisation in the Framework of European policies and legislation which sets out the Commission's priorities in this area. The Communication analyses the current situation and identifies the key areas where the European standardisation system and the instruments available to European standardisation policy can and should be improved further. The Council endorsed this Communication in December 2004. It called for a more extensive use of European standardisation in European policies and legislation, as well as further improvements in the efficiency, coherence and visibility of European standardisation and its institutional framework.

44. Com M/403 Standardisation mandate addressed to CEN, CENELEC and ETSI in the field of Information and Communication Technologies, Brussels 6 March 2007

45. DICOM stands for the Digital Imaging and Communications in Medicine (DICOM) standard - see http://medical.nema.org/.

46. http://www.prorec-france.org/Q-REC_LESSIS/Q-REC.html .

47. Point 9, European Parliament Resolution of 23 May 2007

48. Communication from the commission, Brussels, 26 September 2006, SEC (2006) 1195/4 Consultation regarding Community action on health services http://ec.europa.eu/health/ph_overview/co_operation/mobility/docs/comm_health_services_comm2006_en.pdf

49. Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data, OJ L 281, 23.11.1995, p. 31–50.

50. Directive 2002/58/EC of the European Parliament and of the Council of 12 July 2002 concerning the processing of personal data and the protection of privacy in the electronic communications sector (OJ L 201, 31.7.2002, p. 37–47).

51. See in general: "Communication on the follow-up of the Work programme for a better implementation of the Data Protection Directive", COM(2007) 87 final, p.6.

52. For an example of the Article 29 Working Party's work in the health sector, see e.g. "Working Document on the processing of personal data relating to health in electronic health records (EHR)" (WP131), http://ec.europa.eu/justice_home/fsj/privacy/docs/wpdocs/2007/wp131_en.pdf

53. Regulation (EEC) No 1408/71 of the Council of 14 June 1971 on the application of social security schemes to employed persons, to self-employed persons and to members of their families moving within the Community, as amended by Regulation No. 574/72, Regulation No. 883/2004 and currently negotiated COM(2006) 16 final of 31 January 2006.

54. E. g. ECJ C-120/95, ECJ C-158/96.

55. The selected study started officially in spring 2007.

56. DG SANCO together with TAIEX carried out a two-day training on financing European healthcare on September 21-22, 2006.

57. As an additional step to improving access to finance for the development of businesses, including in services, the Commission and the European Investment Fund have launched an innovative initiative of using structural funds to provide access to finance by small businesses. This so-called JEREMIE ("Joint European Resources for Micro-to-Medium Enterprises") initiative will work within the framework of cohesion policy programmes to support Member States in developing well-designed financial instruments in favour of SMEs, where the EIF is ready to help programme managers in the complex task of developing the provision of different forms of risk capital according to regional needs and prioritiesCOM 2006(502) final Putting knowledge into practice.

58. An example of cooperation between public procurers is found in the SI-Øresund initiative. In early 2006, a partly EU funded cooperation project on hospital procurement was initiated between Region Skåne in southern Sweden and the Capital Region of Denmark. The aim of the project is to break down barriers between public hospital procurement organisations on either side of the Oresund Strait and establish improved conditions for durable and formalised cooperation to optimise hospital procurement and be able to meet suppliers on more equal and up-to-date terms. On a joint platform the Swedish-Danish partners are better equipped to meet challenges and exploit synergies in meeting suppliers at the international level. In addition, the intention is to activate both the educational and the private sectors as a source of inspiration for developing future oriented hospital procurement organisation in the Oresund region. Furthermore, the project partners work together with partners from an equivalent network of procurement organisations in Northern Germany, towards the development of a broader EU project aimed at the establishment of a broader EU network in this field. www.si-oresund.org/in_english.6

59. Gartner: The potential of telemedicine applications, October 2006.

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